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(54) SEPTAL DEFECT CLOSURE APPARATUS

(71) We, ALTON OCHSNER MEDICAL FOUNDATION, a non-profit making Corporation organized under the laws of Louisiana, United States of America, of 1514 Jefferson Highway, New Orleans, Louisiana 70121, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to apparatus for the closure of septal defects or shunts in the intravascular system or the great vessels by means of a positive mechanical structure applied by means of an outer catheter and other associated operative elements working within said outer catheter.

In order to gain a better understanding of the present invention and its particular application, it is noted that the heart is divided into four compartments or chambers, the two upper being the left and right atria and the two lower being the left and right ventricles. The atria are separated from each other by a muscular wall, the interatrial septum, and the ventricles by the interventricular septum.

Either congenitally or by acquisition, abnormal openings, holes or shunts can occur between the chambers of the heart or the great vessels (interatrial and interventicular septal defects or patent ductus arteriosus and aorticopulmonary window respectively), allowing the movement of blood through the opening. The deformity is usually congenital, resulting from a failure of completion of the formation of the septum, or wall, between the two sides during fetal life when the heart forms from a folded tube into a four-chambered, two unit system.

These deformities can carry significant sequelae. For example, with an atral septal defect, blood is shunted from the left atrim of the heart to the right, producing an overload of the right side of the heart. In addition to left-to-right shunts such as occur in patent ductus arteriosus from the aorta to the pulmonary artery, the left side of the heart has to work harder because some of the blood which it pumps will recirculate through the lungs instead of going out to the rest of the body. The ill effects of these lesions usually cause added strain on the heart with ultimate heart failure if not corrected.

Heretofore these intracardiac or extracardiac septal defects have required relatively extensive surgical techniques for correction. In 1938 surgeons first seriously entered the field of attacking congenital heart disease when Gross reported the first ligation of a patent ductus arteriosus. Since that time rapid advances have allowed thoracic surgeons to close not only extracardiac congenital shunts but also shunts between the chambers of the heart. The modern era of extracorporeal circulation began in 1953 when Gibbon first closed an atrialseptal defect, using the heart-lung machine. To date the present method of closing intracardiac shunts, such as atrialseptal defects and ventricular-septal defects, entails the relatively drastic technique of open-heart surgery, requiring opening the chest or sternum and diverting the blood from the heart with the use of a cardiopulmonary bypass. The heart is then opened, the defect is sewn shut by direct suturing with or without a patch of synthetic material (usually of Dacron, (a Registered Trade Mark), Teflon (a Registered Trade Mark), silk, nylon or pericardium), and the heart closed. The patient is then taken off the cardiopulmonary bypass machine, and the chest closed.

In place of direct suturing, it has been suggested that closures of interauricular septal defects could be made by means of a double "button" prosthesis, but open heart surgery was still required. See for example "Closure of Interauricular Septal Defects" by Charles A. Hufnagel et al, The Bulletin Georgetown University Medical Center, Vol. IV, No. 5, Pp. 137—139, Feb.-Mar., 1951; which also cited Swan H.: "Experimental Closure of Interauricular Septal Defects-"—Symposium of Cardiovascular Research, National Institute of Health, Jan. 21, 1950, Washington, D.C. Additional work with such a button-type prosthesis in open heart surgery was also

apparently done by C. P. Bailey, M.D. (see Bailey et al: "Correction of Interventricular Septal Defects," Am. Surgery, 136, 919, 1952; and Bailey: "Surgery of the Heart," Lea and Febiger, Philadelphia, Pp. 366, 1955) and by Yousif D. Al-Naaman, M.D., Department of Thoracic and Cardiovascular Surgery, University of Baghdad, Iraq.

Thus, prior to the present invention, it was only possible to repair septal defects or shunts through open-heart surgery, involving shunting the blood through an artificial pump-oxygenator (heart-lung machine) or at least supplanting the action of the heart itself (mechanical heart) while the heart is being repaired. Moreover, although excellent results have been obtained on simple septal defects by open-heart surgery, there is great risk in open-heart surgery in patients whose heart muscles have been under great strain for long periods of time.

In contrast to the relatively drastic technique of open-heart surgery, the apparatus of the present invention is utilised to close off septal defects or shunts without the need of general anaesthesia or opening of the chest. Instead the operative techniques employed require only a small incision over a vein in the groin or neck under only local anaesthesia, such as is carried out for many routine cardiac catheterizations.

Moreover, the catheter/closure apparatus of preferred embodiments of the present invention allows a cardiologist to close a septal defect at the time of diagnostic cardiac catheterization, if desired. Because of the proposed size of the outer catheter used in the present invention, this would be most reasonably carried out after the age of 4 to 5 years.

According to the present invention there is provided a septal defect closure apparatus for closing off a defect in the septum of, for example, the intravascular system, the apparatus including expansion means comprising at least one umbrella-like expansion structure having a main body expansible between a closed position in which the body is, in use, capable of passing through the defect and an expanded position in which the body is substantially planar so as, in use, to be capable of extending at least generally parallel to the septum for contacting the septum surface around the defect to thereby close the defect, central structure means centrally located within said main body and extending in a direction at least generally perpendicular to the body when the body in the expanded position said expansion structure having an umbrella-like frame structure for expanding the body between its closed and expanded position, the umbrella-like structure having a series of relatively hard strut-like members radially emanating from said central structure means, said strut-like members being resiliently biased to an open position so that said main body is resiliently biased towards its expanded position, the apparatus also including operative means removably connectable to said central structure means for applying, in use, pressure along the extended direction of the central structure means for forcing the distal, end portions of the main body of said expansion structure against the septum to close the defect.

Preferably, said operative means includes an obturator wire having attaching means at its distal end for temporary connection to said umbrella-like structure, said umbrella-like structure having a central hub having a connection means for temporary connection to said obturator wire.

The expansion means may comprise a dual set of said umbrella-like expansion structures for placement on opposite sides of the defect, and wherein said operative means includes an obturator wire having attaching means at its distal end for temporary connection to a first one of the umbrella-like structures, said first one of the umbrella-like structures having on its central structure an obturator connector hub means for temporary connection to said obturator wire; said second umbrella-like structure having a central sleeve which can slide over said obturator wire, said central hub and said central sleeve having locking means for, in use, locking them together through the defect in opposing fashion when on opposite sides of the defect.

In this case, the locking means may comprise a male-female connection between said central hub and said central sleeve, the exterior of said connection means of said central hub forming the male member and the interior of said sleeve forming at least in part the female orifice.

It is noted that the term "catheter" as used herein refers to an instrument, generally tubular in shape, which is inserted into a body cavity, naturally or surgically opened. Several different catheters have been developed in the past, either for experimental research purposes or clinical application. The Mobin-Uddin catheter is one that is used for partial occlusion of the inferior vena cava to prevent pulmonary embolization. This catheter has been described in a publication by Drs. Kazi Mobin-Uddin and James R. Jude in an article entitled "A New Catheter Technique of Interruption of the Inferior Vena Cava for Prevention of Pulmonary Embolism", The American Surgeon, Volume 35, page 889, December 1969. See also U.S. Patent No. 3,540,431 to Dr. Kazi Mobin-Uddin issued November 17, 1970. A similar catheter technique, but using a balloon obstruction instead of an umbrella-type obstruction, is disclosed in the article "Experimental Balloon Obstruction of the Inferior Vena Cava" by Hunter et al, Annals of Surgery, Vol. 171, No. 3, Pp. 315—320, February 1970.

Additionally, in experimental work performed by one of the co-inventors himself, a cardiac catheter with an inflatable disc balloon for interim closure of left-to-right shunts through the ventricular septum was used. This catheter has been described in a publication by Dr. Noel L. Mills et al in an article entitled "Balloon Closure of Ventricular Septal Defect," Supplement I to Circulation, Vols. XLIV, page I—III, May 1971. See also the article by Dr. Harold King et al entitled "Experimental Surgical Repair of Ventricular Septal Defects", Surgery, Vol. 34, pp. 1100—1116, December, 1953.

Diverse examples of other expansible and/or umbrella-like elements generally used in other types of surgical applications are found in the following U.S. Patents:

Patent No.	Inventor(s)	Title	Issue Date
2,493,326	J. H. Trinder	"Tampon for Control of Intractable Nasal Hemorrhages"	30/1/50
2,799,273	V. J. Oddo	"Haemostatic Catheter"	16/7/57
3,334,629	B. D. Cohn	"Occlusive Device For Inferior Vena Cava"	8/8/67
3,397,699	G. C. Kohl	"Retaining Catheter Having Resiliently Biased Wing Flanges"	20/8/68
3,592,184	David H. Watkins Erwin J. Klink	"Heart Assist Method And Catheter"	13/7/71
3,671,979	Spyridon	"Catheter Mounted Artificial Heart Valve for Implanting In Close Proximity To A Defective Natural Heart Valve"	27/6/72

However, as should be fully appreciated and understood from the detailed description of the preferred embodiments below, all of these diverse prior art catheters and umbrella-like elements, neither collectively nor individually, anticipate the present invention.

For a further understanding of the nature and objects of the present invention, reference should be had to the following detailed description, taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals and wherein:

Figure 1A is a schematic illustration of the heart, partially cut away, showing a closure apparatus which does not form part of the present invention closing off an atrial septal defect with two of the catheter operative elements of a catheter/closure system being withdrawn; while

Figure 1B is similar in perspective to Figure 1A showing a typical atrial septal defect (ASD).

Figure 1C is a perspective view of left atrial and right atrial umbrella-like closure elements used for an ASD in their open or erected positions.

Figure 2A is a side view of a left atrial umbrella-like closure element in its collapsed position with the inner, central sliding sleeve shown partially in phantom lines; while

Figures 2B and 2C are side, cross-sectional and end views, respectively, of the inner, central hub of the left atrial umbrella-like closure element of Figure 2A.

Figure 3A is a side view of a right atrial umbrella-like closure element in its collapsed position with the inner, central sliding sleeve shown partially in phantom lines; while

Figures 3B and 3C are side, cross-sectional and end views, respectively, of the inner, central sliding sleeve of the right atrial umbrella-like closure element of Figure 3A.

Figure 4 is a side view of a typical strut element used in left atrial and right atrial umbrella-like closure elements.

Figure 5 is a perspective view of three catheter operative elements, concentrically assembled together.

Figure 6 is a side, perspective view, partially cut away, of the catheter operative elements with the left atrial umbrella-like closure element attached to the central catheter element with the struts thereof partially opened, portions of the umbrella-like element, particularly the covering material, not being illustrated for simplicity purposes; while

Figure 7 is similar to Figure 6 with the exception of showing the right atrial umbrella-like closure element being affixed to the central catheter operative element and showing an additional operative element, a con-

trol disc, positioned on the proximal end of the central catheter operative element.

Figure 8 is a side view of a cone operative element used to initially close the umbrella-like elements prior to their insertion into the outer catheter operative element.

Figures 9A through 9K are side, schematic views of the inner heart structure illustrating the sequential steps of the known apparatus as being applied to the closing of an atrial septal defect (ASD); while

Figures 10A and 10B are respectively, views of the right and left atrial umbrella-like closure elements after being applied and locked together to close off the atrial septal defect.

Figure 11 is a side, cross-sectional view of the central hub and sleeve structures of the left atrial and right atrial umbrella-like closure elements located together in a male-female relationship.

Figure 12 is a side, prespective view of a structure in accordance with the present invention.

Figure 13A is a schematic illustration of the heart, partially cut away, showing a closure apparatus closing off a ventricular septal defect with an alternate method utilizing a single umbrella-like element being used; while

Figure 13B is similar in perspective to Figure 13A showing a typical ventricular septal defect (VSD).

Figure 13C is a perspective view of a single umbrella-like closure element used for a VSD in its open or erected position; while

Figure 13D is a side view of the special obturator wire used in the alternative single umbrella technique.

Figure 14A is a schematic illustration of the heart, partially cut away, showing closure apparatus which does not form part of the claimed invention closing off a patent ductus arteriosus (PDA) using a modified right atrial or second umbrella-like closure element with the final catheter operative element of the catheter/closure apparatus ready to be withdrawn; while

Figure 14B is similar in perspective to Figure 14A showing a typical patent ductus arteriosus (PDA).

Figure 14C is a perspective view of the modified left atrial and right atrial or first and second umbrella-like closure elements used for a PDA in their open or erected positions.

Figure 15A is a side view of a further right atrial umbrella-like element which does not form part of the claimed invention shown mounted on the obturator wire prior to its being applied to the shunt; while

Figure 15B is a side view of the element of Figure 15A as it is being applied to the shunt and being pushed to its locking position with the left umbrella-like element; while

Figure 15C is a close-up, side view of the central portions of the umbrella-like closure elements in their final, locked position.

Figures 16A and 16B are frontal views of the under-side and topside respectively, of a further embodiment of the left atrial umbrella-like closure element of the present invention in its open position for closing an ASD; while

Figures 17A and 17B are frontal views of the underside and topside, respectively, of another embodiment of the right atrial umbrella-like closure element in its open position used with the left atrial umbrella-like closure element of Figures 16A and 16B.

Figure 18 is a side view of the proximal ends of the catheter operative elements used with the closure elements of Figures 16 and 17; and

Figure 19 is a side view of the distal ends of the catheter operative elements of Figure 18 without the umbrella-like closure elements attached; while

Figure 20 is a side view again of their distal ends as in Figure 19 but with the left and right atrial umbrella-like closure elements attached and in their open positions located as they would be on opposite sides of the septum (not illustrated) and prior to being pushed and locked together.

The expansion means of the present invention must be expansible, fulfilling the special requirement of having a first, smaller physical form while it is being inserted through a blood vessel and quite a different, second, larger form when placed in its final location closing and covering the septal defect or shunt. Additionally it must meet the several stringent mechanical requirements placed upon it, must reliably open at the desired time and place, and must effect a suitable tight closure of the defect or shunt in the heart system for a long period of time without any deterioration and without producing any unwanted side-effects either on tissue or blood. Many mechanical systems are conceivable to meet these requirements and preferred embodiments of the present invention, which will now for purposes of illustration and disclosure only be described in detail.

A known type of expansion means as illustrated in Figures 1C, 2 and 3 comprises a pair of opposed, umbrella-like elements 8, 9, the first, left atrial, element 8 having a central, tapered hub 84 and the second, right atrial element 9 having a central, sliding sleeve 94.

The two umbrella-like closure elements 8, 9 have for example six material supporting struts 81, 91, respectively, each (note Figure 4) strut 81, 91 having for example a length of 5.35 mm., with a sixty degree angle between the struts 81, 91 of each element 8, 9. The struts 81, 91 are made of a radio-opaque material (not necessarily metallic), for example stainless steel, which have at the distal ends thereof small projections or barbs

83, 93, respectively, of for example 0.2 mm. length, which allow anchoring of the closure elements 8, 9 into the septum. Three holes are provided along the length of the struts 81, 91—hinge holes 86', 96'; tie eyes 87a, 97a for raising or lowering the struts 81, 91 by means of elevating ties or lines 7; and suture eyes 87b, 97b for attaching the umbrella material 82, 92 to the struts 81, 91. The tie holes 87a, 97a are of sufficient size to allow the ties 7 to slide easily through them.

The struts 81, 91 are attached to the umbrella-like closure elements 8, 9 through a central hub 84 and a sliding sleeve 94, respectively, made of for example stainless steel. The surfaces of the hub 84 and the sleeve 94 are grooved (note Figures 2C and 3C) in such a manner to allow the struts 81, 91, respectively, to lie superficially in their surfaces without adding to the exterior bulk of the umbrella-like structures. The struts 81, 91 are movably attached to the hub 84 and sleeve 94 by hinge ring elements 86, 96, respectively, and there are included ring-like strut keepers 87, 97, respectively, to prevent the struts 81, 91 from opening respectively, beyond ninety degrees. Each umbrella-like element 8, 9 is of small enough size to allow it to be placed within the outer, thin wall catheter 1 within which it is transported during application, as described more fully below.

Thin Dacron (Registered Trade Mark), Teflon (Registered Trade Mark), nylon, Silastic (a Registered Trade Mark), pericardium or silk, for example, routinely used to close intercardiac defects in open-heart surgery, can be used for the umbrella sheet material 82, 92, although Dacron and silk are considered preferable. The material 82, 92 should be pliable and of sufficient strength and resiliency to open and close smoothly. The material 82, 92 is anchored centrally on the hub 84 and the sliding sleeve 94, respectively between the main body thereof and the strut keepers of 87, 97, respectively. Sutures 87b', 97b' can be passed through suture eyes 87b, 97b to secure the umbrella material 82, 92, respectively, distally upon the struts 81, 91. Additionally, supplemental sutures 87a', 97a' can be used if desired to further secure the material 82, to the tie holes 87a, 97a.

The sliding sleeve 94 and the distal hub 84 are designed to lock securely together in opposed, facing relationship by means of an internal, central, male-female mechanism (note particularly Figure 11). A typical structure for achieving this is illustrated particularly in Figure 11 with supplemental reference to Figures 2B and 3B. The hub 84 includes a male member 84' projecting inwardly and having a locking plateau 85 on its outer surface. This mates with the female cavity formed within the inner portion 94' of the sleeve 94. The female cavity also includes a locking groove 95 for mating with the plateau 85.

The total external diameter of the hub 84 is for example 3.3 mm., and it has been engineered with grooves 89 so that the struts 81 may be recessed within the surface. The hub 84 is tapered slightly to a rounded, bullet-shape configuration at one end to a diameter of for example approximately 0.075 mm. The other end of the hub 84 is relatively blunt and has a central threaded orifice 80 for mating with the threaded end 31 of the obturator wire 3, described more fully below. The hub 84 can be for example 3 mm. in length.

Although it has not been found to be necessary, the central sliding sleeve 94 of the right umbrella 9 could have a flared or conical distal end in order to center it automatically with respect to the hub projection 84' as a prelude to sliding up over it and along it to the locked position. The bore 90 of the right sleeve 94 is considerably larger than the diameter of the obturator guide wire 3, described below, to allow for free movement thereon.

The operative elements of the closure catheter apparatus for inserting closure elements comprise several parts: an outer catheter 1; an inner, locking catheter 2; an obturator guide wire 3; a loading cone 4; a manipulating handle 5; and a tie retracting and control disc 6 with a series of elevating ties 7. Note particularly Figures 5, 7, 8 and 9J.

The outer, thin wall catheter 1, for example a No. 24 French size, is of sufficient length (for example 80—105 cm.) to allow its manipulation into the heart area. The outer catheter 1 can be made from thin wall, woven Dacron or preferably polyvinyl material and has a gentle curve at the cardiac end to allow easy manipulation through a septal defect in the cardiac area.

As shown in Figure 5, inside the outer, thin wall catheter 1 is a second, radiopaque, inner catheter 2 which could be for example a No. 5 French size catheter of polyvinyl material. It should be of sufficient length (for example 90—110 cm.) to protrude from the proximal end of the outer catheter 1 and has a rounded, cone-shape distal hub 21 (note Figure 9C). The inner catheter 2 should be of a size to be quite mobile through the outer catheter 1.

Passing through the inner catheter 2 is an obturator guide wire 3 which can be for example 1.1 mm, or less in diameter and have a length of for example 200—350 cm. A removable, proximal handle 5 (note Figure 9J) is used for rotational manipulation of the obturator wire 3. The arm 5 is locked to the obturator wire 3 and is easily removable therefrom by means of a locking set screw

51 going through a central hub element 53. For gripping purposes an extension arm 52 is provided.

The cardiac or distal end 31 of the obturator wire 3 is threaded for approximately 1 mm. so that it may be screwed and unscrewed into the hub 84 of the left closing umbrella 8. The obturator wire 3 should be of sufficient flexibility to allow easy manipulation and can be for example made of a fixed core stainless steel spring material.

As shown in Figure 7, a control disc 6 is provided for ease in manipulating and controlling the ties or lines 7. The disc can be made of stainless steel and is placed on the exterior, proximal portion of the obturator wire when needed. A series of hole pairs 61 are provided about the periphery of the disc for holding the ties 7. Although not illustrated, the holes 61 could be numbered or coded to the particular struts involved and an additional pair of holes can be provided for retracting ties 7'. The ties 7, 7' can be made of for example monofilament nylon or 3—0 silk.

The final operative element is the loading cone 4, illustrated in Figure 8. The loading cone 4 is provided to assist in the easy loading or insertion of the umbrella-like elements 8, 9 into the outer catheter 1. For example, as shown in Figure 8, the left umbrella 8, threaded onto the distal end 31 of the obturator wire 3 and in its open or partially opened position, is first inserted through the loading cone 4 which leads into the outer catheter 1. The cone 4 serves to close the umbrellas 8, 9 making them of a small enough size for insertion into the outer catheter 1.

The distance across the total closure structure from hub tip to sleeve tip (note Figure 9K) once locked in place is only approximately 3.5 mm., elements can be produced in diameter sizes of for example 10 mm., 15 mm., 20 mm., 25 mm., 30 mm. and 35 mm. as desired or needed.

In the present invention rather than dual, opposed umbrellas, a single umbrella could be used as described more fully below with respect to the repair of a ventricular septal defect.

Additionally the present invention provides alternative means of expanding or opening the umbrella. In one embodiment of the present invention, as generally illustrated in Figure 12, the struts 91'' are made of resilient, flexible material so that the umbrella will inherently or automatically open once it emerges from the outer catheter (note the movement of the phantom lined strut).

An additional type of the right atrial umbrella which does not form part of the claimed invention is shown in Figures 15A—C in which the necessity of a tie wire system is eliminated. The umbrella 209 is similar in general structure to the right umbrella 9 except that in place of the tie wire system there is included a set of elevating struts 291' hingedly attached between the regular umbrella struts 291 and an elevating sleeve 294'. As shown in Figure 15B, as the elevating sleeve 294' comes into contact with the hub 84, the umbrella becomes erected under the continuing pressure of the inner catheter 2 until it is locked into place as shown in Figure 15C.

For purposes of illustration and disclosure purposes only, the method of application of closure apparatus will now be described in detail with respect to the closing of an atrial septal defect (ASD) with particular reference to Figures 1A—C and 9A—K.

In order to gain access to the heart, an incision is made in either the right or left groin under local anaesthesia, and the femoral vein isolated. Standard catherization techniques are then utilized to confirm the presence of the ASD such as the one shown in Figure 1B. Once confirmed, sizing of the ASD is then achieved by means of special but standard balloon catheters, and the appropriate size of umbrella-like closure elements 8, 9 are selected.

The initial closing/catheter assembly (note Figure 5), i.e. elements 1, 2 and 3, the latter having the left umbrella 8 attached to its threaded end 31, is then inserted via the femoral vein into the heart under continuous fluoroscopic control into the right atrium. With further advancing of the catheter assembly, it is placed in the left atrium (note Figure 9A).

By manipulating the obturator wire 3, the distal hub 84 carrying the collapsed left umbrella 8 is advanced beyond the outer, thin wall catheter 1 into the left atrium (Figure 9B). Once the left umbrella 8 is pushed beyond the tip of the outer, thin wall catheter 1, the umbrella 8 is initially unfolded by pushing the inner catheter 2 against the struts 81 and holding fast the obturator wire 3 (Figure 9C), expanding the umbrella out in excess of the diameter of the outer catheter 1.

Then by pulling gently on the obturator wire 3, the umbrella 8 is pulled against the distal end 11 of the outer catheter 1, opening the umbrella 8 to its full ninety degree position (Figure 9D). The outer catheter 1 is then pulled back into the right atria and the umbrella 8 pulled snugly against the left atrial wall of the septum, with the barbs 83 being anchored against the septum (Figure 9E).

Once the left umbrella 8 is firmly fixed, the inner catheter 2 is withdrawn and removed and the right umbrella 9 slid onto the obturator wire 3 and loaded into the outer catheter 1 with the elevating ties 7 and retracting ties 7' in place on the struts 91 and sleeve 94, respectively, and the disc 6 (note Figure 7). The collapsed right umbrella 9

is then pushed through and out of the outer catheter 1 by means of the inner catheter 2 into the right atrium and positioned just superior to the inferior vena cava and right atrial junction (Figure 9F). At this point the outer catheter 1 is withdrawn to allow the right umbrella 9 to lie freely upon the obturator guide wire 3 within the body of the right atrium.

As the inner catheter 2 is advanced and traction maintained on the elevating ties 7 and on the retracting ties 7', the right umbrella 9 is opened (Figure 9G) and pushed snugly against the inter-atrial septum by means of the inner catheter 2. By fluoroscopic monitoring, it can be determined that all six struts 91 are at right angles. The inner catheter 2 is pushed further forward, forcing the sliding sleeve 94 of the right umbrella 9 to slide onto the left umbrella hub 84, locking the two together (Figure 9H). A clicking sensation is felt through the obturator wire 3, and a click can be heard as the umbrellas 8, 9 are locked into place. Once in place the umbrellas 8, 9 are tugged gently with the obturator guide wire 3 to assure stability.

Once the umbrellas 8, 9 are locked in place, the obturator wire 3 can be unscrewed from the distal hub 84, using the handle 5 on the proximal portion of the obturator wire 3, thus leaving in place the distal hub 84 with the right and left umbrellas 8, 9 locked in place (Figure 9J). The obturator guide wire is thus unthreaded with the aid of the handle 5 from the left umbrella hub 84 and removed from the heart with the outer and inner catheters 1, 2 (Figure 9K). Following this, the outer, thin wall catheter 1, the inner catheter 2 and the obturator wire 3 are completely withdrawn from the body.

Following installation of the closure structure, a diagnostic venous catheter can be introduced for the appropriate angiograms, dye curves and hydrogen electrode studies to confirm the effectiveness of the closure of the septal defect. The closure structures 8, 9 should be covered by endocardium within six to eight weeks, and be thereby integrated into the heart's structure.

After completion of the operation, the vein and inguinal incision are closed.

For purposes of further illustration and disclosure, the method of application of closure apparatus will now be described in some detail with respect to the closing of a ventricular septal defect (VSD) with particular reference to Figures 13A—C.

In order to gain access to the heart, an incision is made in the right neck over the external or internal jugular vein under local anaesthesia. The jugular vein is isolated and venotomy is made for insertion of the outer catheter 1. Standard catherization techniques are then utilized to confirm the presence of the VSD such as the one shown in Figure 13B. Once confirmed, sizing of the VSD is then achieved by means of special but standard balloon catheters, and the appropriate size of the umbrella-like closure element 8' is selected.

The outer catheter is inserted into the vein and subsequently passed into the right ventricle and manipulated across the ventricular septal defect into the left ventricle. Its position can be documented by obtaining an oxygen sample or passing an NIH catheter through the outer catheter into the left ventricle and doing a hand injection.

The proper size umbrella 8' similar in structure to the left atrial umbrella 8 described above is loaded into the outer catheter and passed into the left ventricle and opened by using the inner catheter in the same manner as is carried out in closing the atrial septal defect as described above. The opened umbrella 8' is pulled snugly against the left side of the interventricular septum adjacent to the ventricular septal defect.

The outer and inner catheters are then removed from the body, leaving the obturator wire 3, and Silastic (A Registered Trade Mark) tubing 3' is passed over the obturator wire 3 and subsequently into the heart to entirely cover the exposed obturator wire 3.

By maintaining general pressure on the obturator wire 3, the umbrella 8' is held tightly against the left side of the interventricular septum and thus closes the interventricular septal defect. The umbrella 8' is maintained in place by the barbs on the tips of the struts (like those described above) and by the obturator wire 3. Additionally the internal blood pressure system, which is greater in the left ventricle than the right (typically 90 min. Hg vs. 30 min. Hg) serves to help maintain the umbrella 8' over the VSD, closing it off.

The tubing 3' and the wire 3 are cut off at the appropriate lengths to allow anchoring them in the tissues of the right neck within the jugular vein. The incision is closed, and periodic checks are made of the umbrella 8' over the subsequent 15 minutes by fluoroscopy.

The patient is anticoagulated prior to the installation of the ventricular closing umbrella and is maintained on anticoagulation therapy for several weeks. After about six to eight weeks and the umbrella 8' has been endothelialized, an incision is again made over the proximal end of the tubing 3' and wire 3 (quite close to the original incision in the neck). The wire 3 and tubing 3' is isolated, and with the use of the handle 5 on the proximal end of the obturator wire 3, the latter is unscrewed and removed from within the heart and vascular system. The tubing 3' is of course removed simultaneously with the

wire 3, and the incision closed leaving the VSD permanently closed.

Thus, the ventricular septal defect is closed with the use of only a single umbrella 8' with temporary anchoring by the wire 3 covered with the tubing 3' to prevent clotting and embolization.

To close a patent ductus arteriosus (PDA), for example like that shown in Figure 14B, the same analogous method discussed with respect to the ASD of Figure 1B and the steps of Figures 9A—K can be used. However, because of the longer distance between the aortic and pulmonary outer walls of the PDA, modified aortic and pulmonary umbrella elements 108, 109 are used in place of the left and right atrial umbrella elements 8, 9. The main modification is to extend further out the male member of the aortic umbrella 108 or alternatively the female member 194 (as illustrated in Figure 14C). Otherwise the structure of the umbrellas 108, 109 can be identical to that disclosed in detail above with respect to the umbrellas 8, 9.

It is noted that it is advantageous to use the closure structures of the present invention even when open-heart surgery is necessary, as for example in the case of small babies. In such cases, the closure structures of the present invention can be applied through the open heart in a matter of a few minutes as opposed to the typical thirty to forty minutes usually taken with standard suturing of the shunt as practised in the prior art.

The closure elements and the catheter operative elements and their method of application described in detail with respect to Figures 1C—11 were initially developed and experimentally tested with dogs with success. Further development work has produced the embodiment of the present invention shown in Figures 16A—20 which is expected to be applied to human patients in the very near future and which will now be described in detail.

As shown in Figures 16A & B and 17A & B, for an ASD there is provided two umbrella-like closure elements, a left atrial one 308 and a right atrial one 309, each having for example six material supporting struts 381, 391, respectively.

The struts 381, 391 are made of a radio-opaque material (not necessarily metallic), for example stainless steel, and as illustrated are each initially flat in radial plane and then are twisted ninety degrees so that they are then flat in the plane of the septum. The struts 381, 391 are hingedly attached to a central hub 384 and a sliding sleeve 394, respectively, also made of for example stainless steel. The surfaces of the hub 384 and the sleeve 394 are grooved to hold the struts 381, 391.

As noted above, thin Dacron (Registered Trade Mark), Teflon (Registered Trade Mark), nylon, Silastic (Registered Trade Mark), pericardium or silk, for example, can be used for the umbrella sheet material 382, 392 which is sutured to the struts 381, 391, respectively.

The sliding sleeve 394 and the distal hub 384 are designed to lock securely together in opposed, facing relationship by means of an internal, central, male-female mechanism, as described above with respect to the previously described closure elements (note for example Figure 11).

Like the embodiment of Figure 12, the struts 381, 391 are designed to be self-opening by the use of a resilient structure. In the embodiment of Figures 16 and 17, this inherent resiliency is provided by the addition of a thin, resilient, springy ring 387, 397, of for example Silastic (Registered Trade Mark) material attached to the struts which causes them to automatically spring out when they are no longer constrained or under restraint. Suitable dimensions for the ring 387, 397 for an umbrella-like closure element of two cm. diameter is a ring having an outer diameter of 8 mm. and a thickness of 0.5 mm. The resilient members 387, 397 can take on various forms besides a ring, such as for example a disc or individual arms (not illustrated).

As before with respect to the closure apparatus of Figure 5, the operative elements of the closure catheter system for the umbrella-like closure elements of Figures 16 and 17 comprise several parts: (note Figures 18—20) an outer catheter 301, an inner, locking or right atrial catheter 302, and an obturator wire 303. However, in this embodiment, the outer catheter 301 includes at its distal end a housing capsule 310 which is used to house both closure elements 308, 309 as the catheter is inserted into the body in juxtaposition to the septal defect to be closed. Additionally the distal end of the inner, locking catheter includes a terminal threaded portion 321 (in place of the distal hub 21 of inner catheter 2) which mates with a similarly threaded female orifice in the sliding sleeve 394, which allows positive, detachably fixed movement of the right umbrella-like element 309 on the end of the inner catheter 302. At the proximal end of the inner catheter 302, there is provided a "manipulating-stop" hub 302' which prevents the proximal end of the inner catheter from going into the outer catheter 301 and allows the inner catheter 302 to be easily manipulated for the twisting, pushing or pulling thereof.

As before, the left umbrella-like element 308 is detachably fixed by threaded engagement to the threaded portion 331 on the distal end of the obturator wire 303. As illustrated in Figure 19, the terminal distal section of the obturator wire 301 can include a built-up portion 301' for strengthening purposes.

The method of application of the embodiment of Figures 16—20 is similar to that disclosed with respect to Figures 9A—9K except that the closed umbrella-like closure elements 308, 309 fastened to the distal ends of the obturator wire 303 and the inner catheter 302, respectively, are both initially placed in line in the distal capsule 310. The loaded capsule 310 then is inserted through the body in juxtaposition to the septal defect in the position analogous to that shown in Figure 9A. The left closure element 308 is pushed out of the capsule 310 until it is clear thereof, at which point the struts 381 automatically open under the spring action of the resilient ring 387. The outer catheter 301 is then pulled back into the right atria, and the open closure element 308 gently pulled snugly against the left atrium septum (analogous to the action illustrated in Figure 9B).

Once the left closure element 308 is firmly in position, the right closure element 309 by means of the inner catheter 302 is moved out of the distal capsule 310 until it is clear thereof, at which point the struts 391 automatically open under the spring action of the resilient ring 397. The inner catheter 302 with the open right closure element 309 on the end thereof is pushed further forward, riding over the obturator wire 303 and forcing the sliding sleeve 394 of the right closure element 309 to slide onto the left closure element hub 384, locking the two together (analogous to the action illustrated in Figure 9H).

Once the umbrella-like elements 308, 309 are locked in place, the obturator wire 301 and the inner catheter 302 can be unscrewed from them and, with the outer catheter 301, completely withdrawn from the body. To insure that the closure elements 308, 309 are securely locked, the inner catheter 302 is unscrewed first and the two umbrella-like structures 308, 309 moved to-and-fro by means of the obturator wire 303 and the action viewed by fluoroscopy.

Other than the differences in structure and method outlined above, the embodiments are at least generally the same and reference is had to the more detailed description of the closure apparatus of Figures 1C—11 for further detailed understanding of the embodiment of Figures 16—20.

Thus atrial septal defects (Figure 1) and in similar fashion ventricular septal defects (Figure 13) and great vessel shunts (Figure 14) are closed by non-invasive techniques.

From past experience with cardiac surgery, stainless steel, particularly of the 300 series, which is the preferred materials for all structural parts remaining in the heart, and materials such as Dacron (Registered Trade Mark), Teflon (Registered Trade Mark), nylon, pericardium, Silastic (Registered Trade Mark) and silk can be permanently inserted within the heart and tolerated without adverse effects. It is estimated that the heart will endothelialize the closure elements within six to eight weeks as occurs after standard shunt closures using open-heart surgery.

Because many varying and different embodiments may be made within the scope of the appendent claims, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirements of the law, it is to be understood that the embodiments herein are to be interpreted as illustrative and not in a limiting sense.

WHAT WE CLAIM IS:—

1. A septal defect closure apparatus for closing off a defect in the septum of, for example, the intravascular system, the apparatus including expansion means comprising at least one umbrella-like expansion structure having a main body expansible between a closed position in which the body is, in use, capable of passing through the defect and an expanded position in which the body is substantially planar so as, in use, to be capable of extending at least generally parallel to the septum for contacting the septum surface around the defect to thereby close the defect, central structure means centrally located within said main body and extending in a direction at least generally perpendicular to the body when the body in the expanded position said expansion structure having an umbrella-like frame structure for expanding the body between its closed and expanded position, the umbrella-like structure having a series of relatively hard strut-like members radially emanating from said central structure means, said strut-like members being resiliently biased to an open position so that said main body is resiliently biased towards its expanded position, the apparatus also including operative means removably connectable to said central structure means for applying, in use, pressure along the extended direction of the central structure means for forcing the distal, end portions of the main body of said expansion structure against the septum to close the defect.

2. Apparatus as claimed in Claim 1 wherein said operative means includes an obturator wire having attaching means at its distal end for temporary connection to said umbrella-like structure, said umbrella-like structure having a central hub having a connection means for temporary connection to said obturator wire.

3. Apparatus as claimed in Claim 1 or 2, wherein said expansion means comprises a dual set of said umbrella-like expansion structures for placement on opposite sides of the defect, and wherein said operative means includes an obturator wire having attaching means at its distal end for temporary connec-

tion to a first one of the umbrella-like structures, said first one of the umbrella-like structures having on its central structure an obturator connector hub means for temporary connection to said obturator wire; said second umbrella-like structure having a central sleeve which can slide over said obturator wire, said central hub and said central sleeve having locking means for, in use, locking them together through the defect in opposing fashion when on opposite sides of the defect.

4. Apparatus as claimed in Claim 3, wherein said locking means comprises a male-female connection between said central hub and said central sleeve, the exterior of said connection means of said central hub forming the male member and the interior of said sleeve forming at least in part the female orifice.

5. Apparatus as claimed in Claim 4, wherein said male member includes a projection on its mating surface and said female orifice includes an indentation for further mating with said projection and locking the hub and sleeve together.

6. Apparatus as claimed in any one of the preceding claims wherein said strut-like members are made of resilient material to provide the resilient biasing.

7. Apparatus as claimed in any one of Claims 1 to 6 wherein the or each of said expansion structures has on its distal portions anchoring means for anchoring said expansion structure to the septum when said expansion structure is forced against the septum.

8. Apparatus as claimed in Claim 7 wherein said anchoring means comprises projections extending at least partially in a direction parallel to said extended central structure means and hence, in the installed condition of the apparatus, parallel to the central axis of the defect and perpendicular to the septum surface, said projections being barb-like structures.

9. A septal shunt defect closure apparatus substantially as described herein with reference to and as illustrated in Figure 12 or Figures 16A to 20 of the accompanying drawings.

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14 SHEETS

COMPLETE SPECIFICATION

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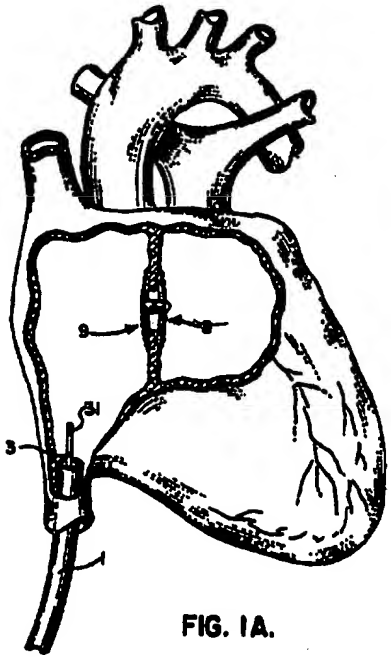


FIG. 1A.

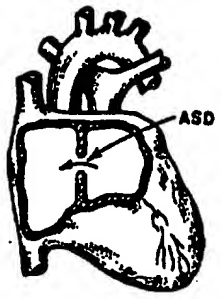
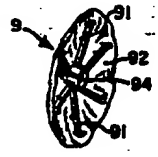
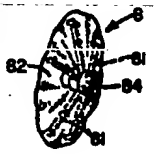


FIG. 1B.

FIG. 1C.





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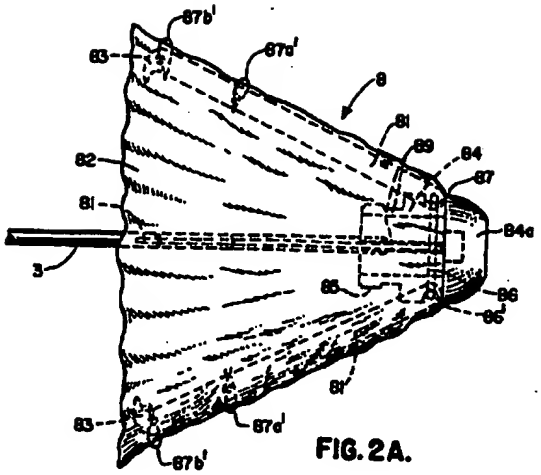

FIG. 2A.

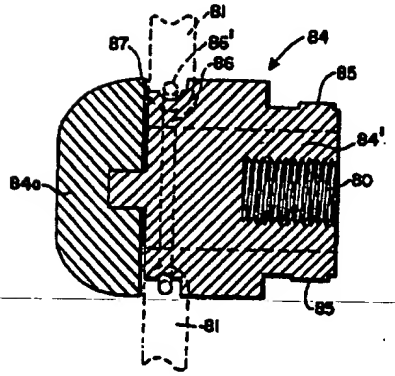

FIG. 2B.

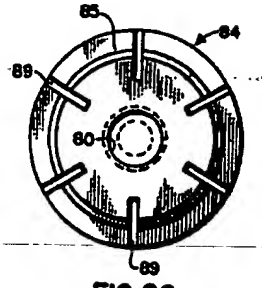

FIG. 2C.

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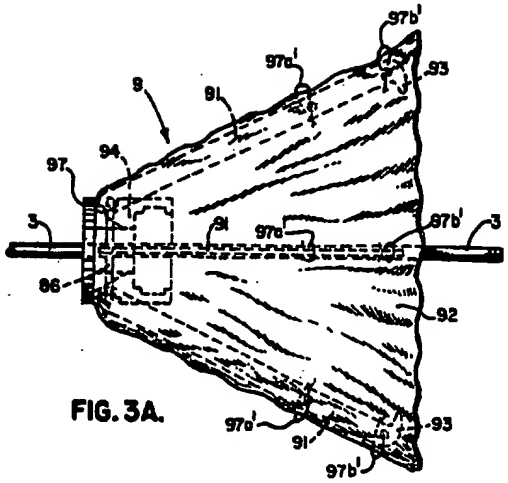

FIG. 3A.

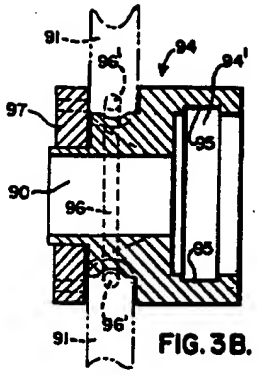

FIG. 3B.

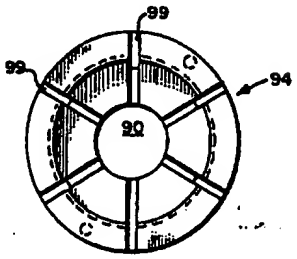

FIG. 3C.

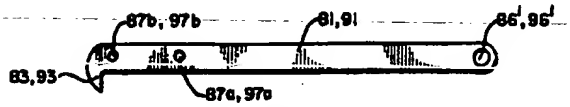

FIG. 4.

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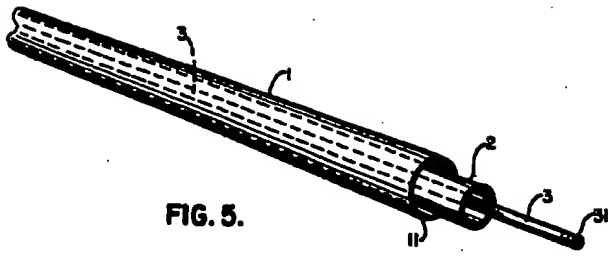

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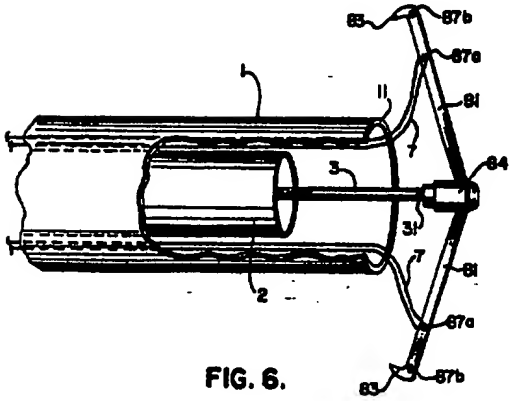

FIG. 6.

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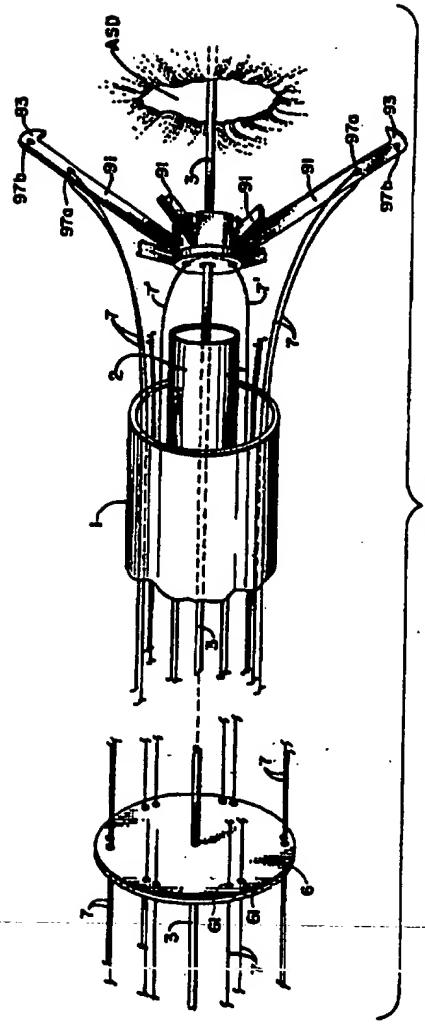

FIG. 7.

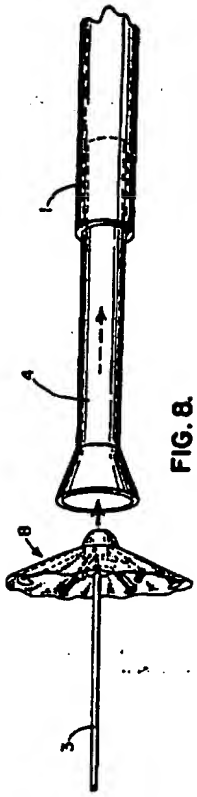

FIG. 8.

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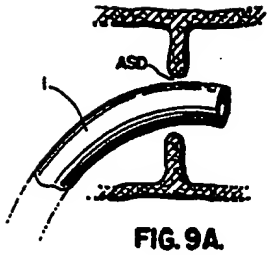

FIG. 9A.

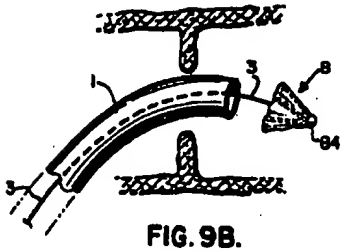

FIG. 9B.

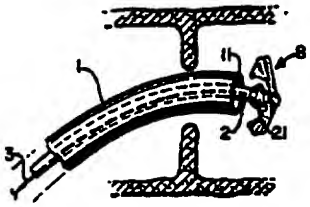

FIG. 9C.

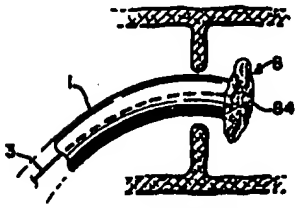

FIG. 9D.

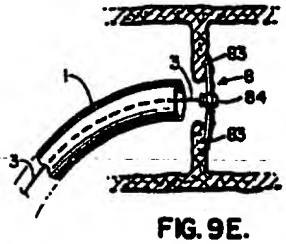

FIG. 9E.

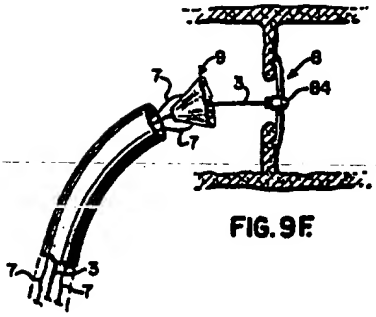

FIG. 9F.

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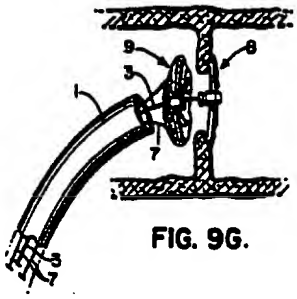

FIG. 9G.

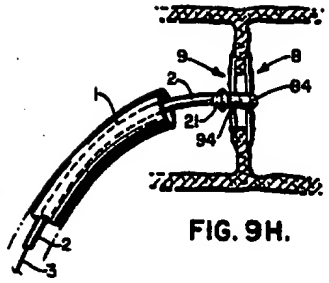

FIG. 9H.

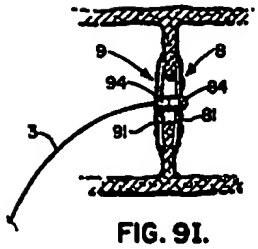

FIG. 9I.

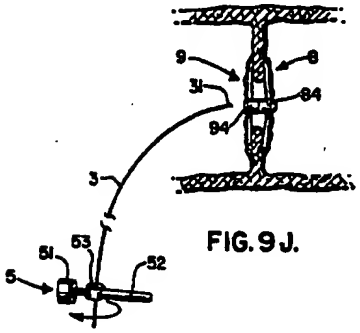

FIG. 9J.

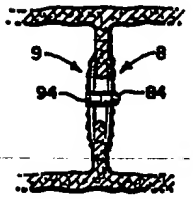

FIG. 9K.

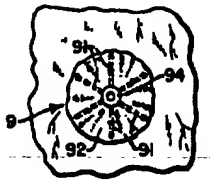

FIG. 10A.

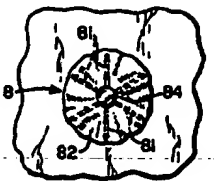

FIG. 10B.

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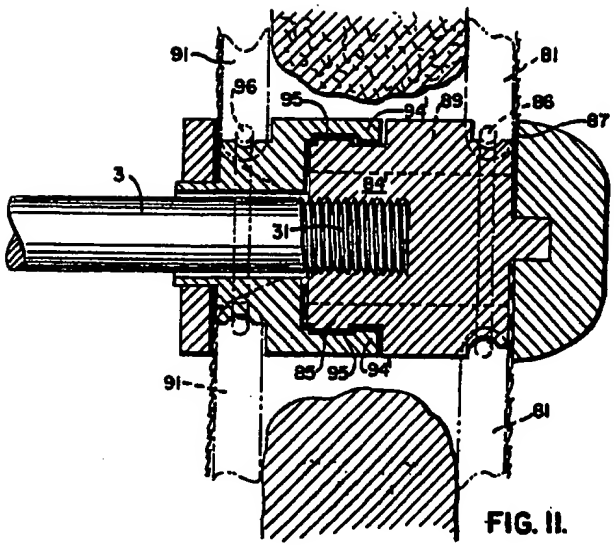

FIG. 11.

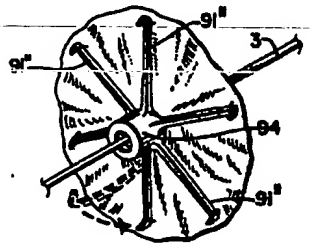

FIG. 12

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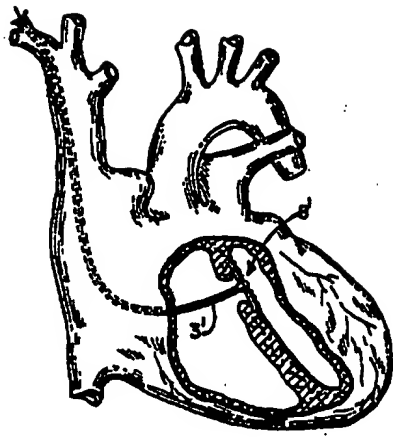

FIG. 13A.

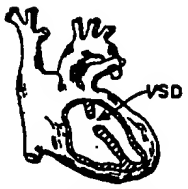

FIG. 13B.

FIG. 13C.

FIG. 13D.

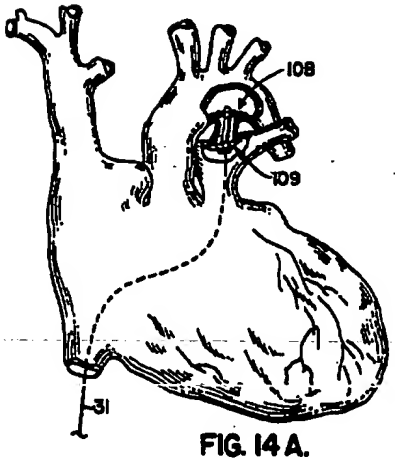

FIG. 14A.

FIG. 14B.

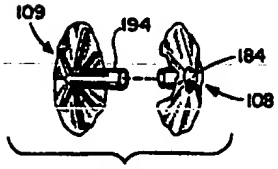

FIG. 14C.

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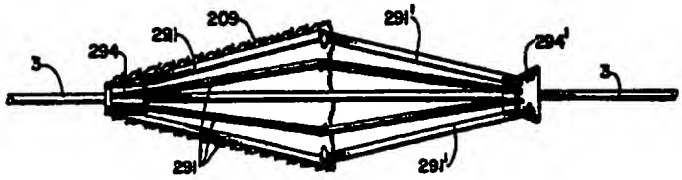

FIG. 15A.

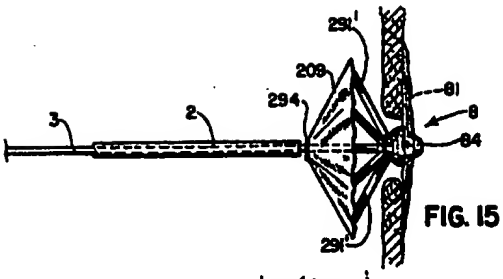

FIG. 15B.

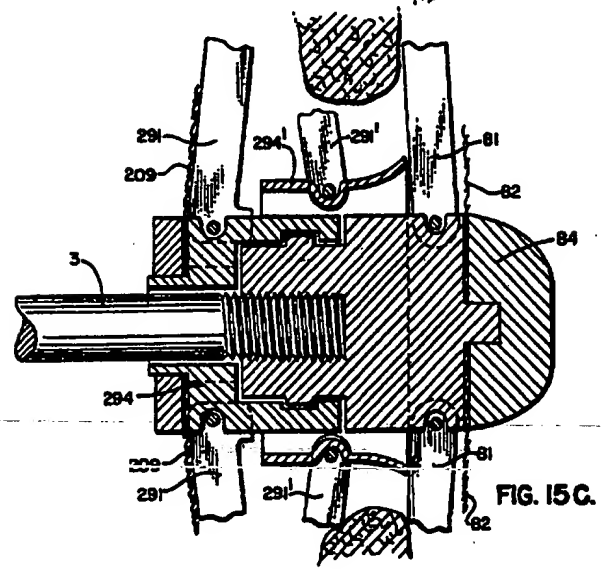

FIG. 15C.

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14 SHEETS

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Sheet 11

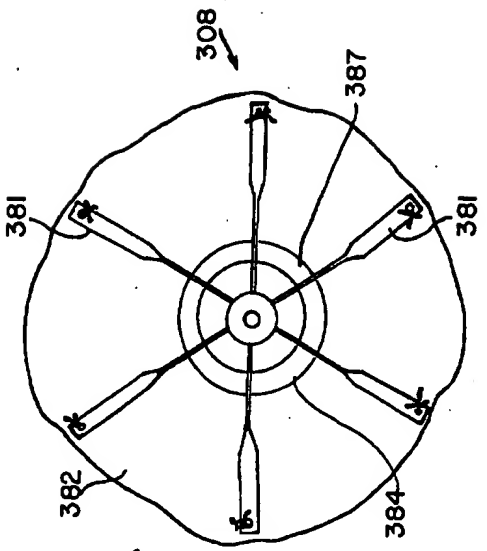

FIG. 16A

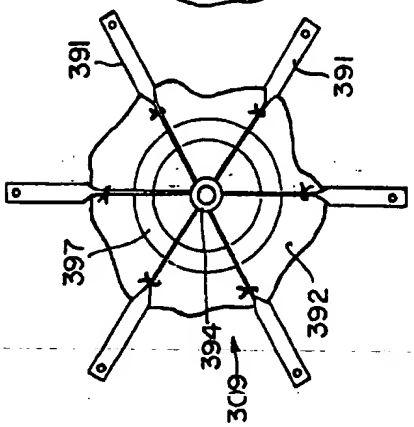

FIG. 17A

1509023 COMPLETE SPECIFICATION
14 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 12

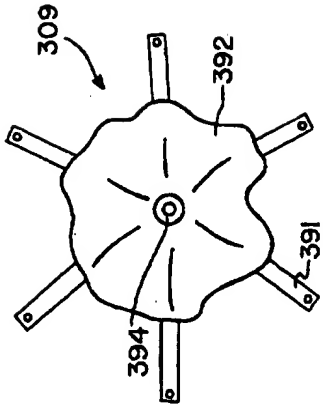

FIG. 17B

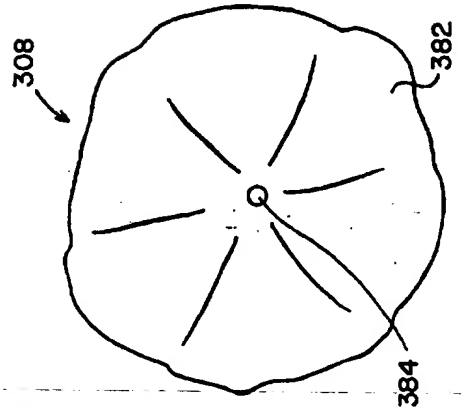

FIG. 16B

1509023 COMPLETE SPECIFICATION
14 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 13

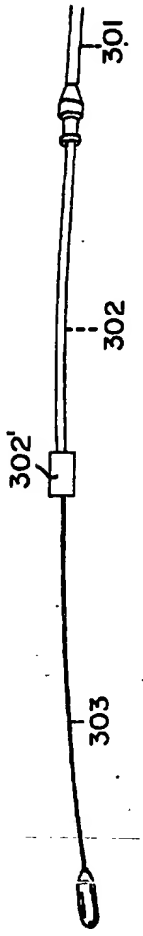

FIG. 18

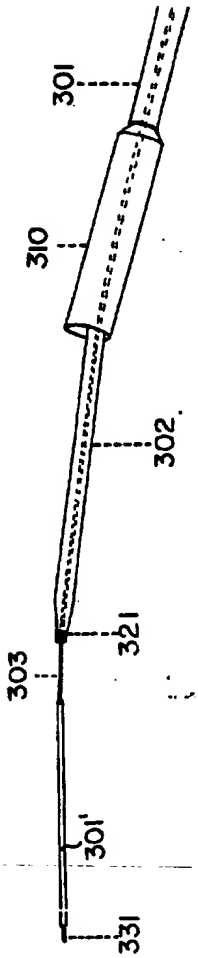

FIG. 19

1509023 COMPLETE SPECIFICATION
14 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 14

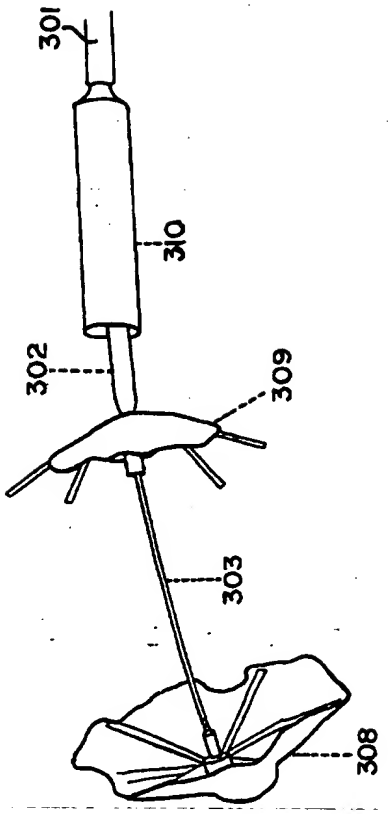

FIG. 20